

K964608

510(k) Summary

FEB - 4 1997

1. **DEVICE NAME:** Magnetic Resonance Device Accessory
Model Number MRT-35A v9.0
Trade/Propriety Name: MRT-35A v9.0
2. **ESTABLISHMENT REGISTRATION:** 2936923
3. **U.S. Agent Name and Address:** Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, California 94080

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4. **Manufacturing Site** Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, California 94080
5. **DATE OF SUBMISSION:** November 15, 1996
6. **DEVICE DESCRIPTION**

The MRT-35A v9.0 is a modification of the MRT-35A system which uses a 0.35T superconducting magnet. The MRT-35A v9.0 is an incremental upgrade to an MRT-35A system which is configured with version 8 hardware and software. The 9.0 upgrade replaces the version 8 computer system. The computer architecture, operational characteristics and user software follow the same design considerations cleared by Flexart™ and Visart™ systems. This 9.0 upgrade makes no change to the MRT-35A version 8 series magnet, gradient system or coil set.

7. SAFETY PARAMETERS

	<u>MRT-35A</u> <u>9.0 Upgrade</u>	<u>MRT-35A</u> <u>8.0 Upgrade</u>	<u>Flexart™</u>
Maximum static field strength:	0.35 T	same	0.5 T
Rate of change of magnetic field:	6.83 T/sec	same	11 T/sec
Max. radio frequency power deposition:	0.3 W/kg	0.34 W/kg	<0.256 W/kg
Acoustic Noise levels:	110.4 db (max)	101.6 db (max)	100.2 db (max)

510(k) Summary (cont'd)

8. IMAGE PERFORMANCE PARAMETERS

		MRT-35A	MRT-35A	<u>Flexart™</u>
		<u>9.0 Upgrade</u>	<u>8.0 Upgrade</u>	
Specification Volume:	Head:	10cm dsv	10cm dsv	10.4cm dsv
	Body:	20cm dsv	20cm dsv	10.4cm dsv

Sample phantom images and clinical images were presented for all new sequences, demonstrating conformance with consensus standards requirements for Signal-to-Noise ratio, Uniformity, Slice Profiles, Geometric Distortion and Slice Thickness/Interslice Spacing.

9. INTENDED USE

- | | |
|-----------------------|--|
| 1. Anatomical region: | Head, Body, Spine, Neck, TMJ, and Heart |
| 2. Nuclei excited: | Hydrogen |
| 3. Diagnostic Uses: | Imaging of the whole body (including the head, abdomen, heart, pelvis, spine, blood vessels, limbs and extremities), fluid visualization, 2D/3D Imaging, MR Angiography, MR Fluoroscopy. |

10. EQUIVALENCY INFORMATION

Toshiba America MRI, Inc. (TAMI) believes the MRT-35A v9.0 is substantially equivalent to the MRT-35A with Version 8.0 series upgrade and Flexart™ diagnostic magnetic resonance systems because it consists of hardware and software modifications that do not introduce new questions of safety or efficacy, nor does it introduce new indications for use. The MRT-35A Version 8 upgrade was cleared by K945798 and its latest software Version 8.5CD is described in K961842. The Flexart™ was cleared by K933018 and its latest software V3.1 is described in K962138. Operationally, the MRT-35A version 9.0 upgrade is based on the software technology of the Flexart™. The MRT-35A Version 9.0 Upgrade makes no change however, to the superconducting magnet, gradient coil, gradient power, MRT-35 coil set or patient couch from the prior MRT-35A upgrade: Version 8. The computer system, applications software, sequences and user console electronics compose is changed in the MRT-35 9.0 Upgrade and these components are based on those found in Flexart™. Manufacturing Practices requirements and software development procedures are unchanged from those already in effect for the Flexart™.